APR 2 0 2001

K010631

synergetics, inc.

PREMARKET NOTIFICATION
510(k) SUMMARY
[As required by 21 CFR 807.92(c)]

Prepared by: Alan Beckman
Director of Quality Assurance and Regulatory Affairs

Contact Person: Same

Preparation Date: February 28, 2001

Device Name: Aspirator tips for ultrasonic surgical instrument systems

Proprietary/Trade Name: Synergetics, Inc. Sonotome™ Ultrasonic Aspirator Tips

Common/Usual Name: Ultrasonic aspirator tips

Classification Name: Instrument, Ultrasonic Surgical

The following table provides a summary of the safety and effectiveness comparison between the predicate device and the proposed device:

Name:	Predicate Device CUSA Excel Ultrasonic Surgical Aspirator	Proposed Device Synergetics Sonotome Ultrasonic Aspirator Tips	Safety & Effectiveness Comparison
Intended Use	Indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue is desirable.	Indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue is desirable.	No difference in intended use. No safety or effectiveness issues identified.
Materials and Assembly Methods	Tips made of 6AL-4V Titanium. Tips are drawn and machined from one solid piece of titanium.	Tips made of 6AL-4V Titanium. Tips are drawn and machined from one solid piece of titanium.	Identical in material and construction. No safety or effectiveness issues identified.
Packaging	Supplied non-sterile in packages of four individual tips. Also supplied in a procedural kit.	Supplied sterile in packages of five. Individual tips are supplied in a Tyvek peel pouch.	Terminal sterilization of the proposed device prior to distribution should provide greater flexibility for the surgeon to change tips during the procedure if necessary.

Synergetics Sonotome™ Ultrasonic Aspirator Tips are accessories that are attached to the handpiece of an ultrasonic surgical aspirator system manufactured by another company. The tip, which simply transmits power from the system handpiece, is an ultrasonically vibrating surgical device which, in combination with irrigation and aspiration, fragments, emulsifies and removes unwanted tissue. It allows the selective dissection of target tissues while preserving vessels, ducts and other delicate structures. The main features on

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Aspirator Tips are:

- A variety of tip diameters, shapes and lengths are available for specific surgical applications.
- Curved tips are bent so as to provide clear visualization of the surgical site, unobstructed by the handpiece.
- Individually packaged, sterile tips can be replaced without the need for resterilization of the handpiece.
- Preaspiration holes in the tips minimize clogging and keep the tip clear of debris.

Validation and verification of the Ultrasonic Aspirator Tips will be accomplished through a combination of analysis and testing. This process will include a Risk Analysis and a mechanical performance test on prototype units.

The biological safety of the Ultrasonic Aspirating Tips has been assured through the selection of materials that demonstrate appropriate levels of biocompatibility. The material used (6AL-4V titanium, AMS4928) is the same as the material that is used in the predicate device and in other similar existing systems that are commercially available in the United States.

Intended Use:

Synergetics Sonotome™ Ultrasonic Aspirator Tips are intended for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue is desirable, including:

- Neurosurgery
- Gastrointestinal and Affiliated Organ Surgery
- Urological Surgery
- Plastic and Reconstructive Surgery
- General Surgery
- Orthopedic Surgery
- Gynecological Surgery
- Thoracic Surgery
- Laparoscopic Surgery
- Thoracoscopic Surgery

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Alan T. Beckman
Director of Quality and Regulatory Affairs
Synergetics, Inc.
88 Hubble Drive
St. Charles, Missouri 63304

Re: K010637
Trade Name: Synergetics, Inc. Sonotome™ Ultrasonic Aspirator Tips
Regulatory Class: Unclassified
Product Code: LFL
Dated: March 2, 2001
Received: March 5, 2001

Dear Mr. Beckman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number: K010637

Device Name: Sonotome Ultrasonic Aspirator Tips

Indications for Use:

Synergetics' Sonotome™ Ultrasonic Aspirator Tips are intended for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue is desirable, including:

- Neurosurgery
- Gastrointestinal and Affiliated Organ Surgery
- Urological Surgery
- Plastic and Reconstructive Surgery
- General Surgery
- Orthopedic Surgery
- Gynecological Surgery
- Thoracic Surgery
- Laparoscopic Surgery
- Thoracoscopic Surgery

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR §801.109)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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